Injector Device For Infusion Set

The technical field

The invention relates to an injector device for an infusion set for intermittent or continuous administration of a therapeutical substance, such as insulin. An infusion set comprises an infusion part with a cannula to penetrate the skin of a person and a connector for connecting the infusion part with a medical device preferably a medical delivery device such as an insulin pump.

The infusion set has in its assembled form a substantially planar rear side and a relatively large width compared to its thickness, thus allowing it to lie flat on the patient's skin and thereby minimizing the discomfort of carrying the infusion set.

The injector device according to the present invention is especially directed towards situations where patients wants to or has to insert the infusion part by themselves without the assistance of educated personnel.

Prior art

US 5 522 803 discloses an infusion set having an infusion part and a connector. The infusion part comprises a soft plastic cannula in liquid communication with a cavity for receiving a needle from a connector, two sloping guiding holes and two retention devices; and the connector comprises a cannula, two square guiding pins and two arms with a hooking part for gripping the retention device of the infusion part and operating in the main plane of the infusion part.

A lot of patients e.g. insulin patients have to or may desire to insert an infusion device or to place a subcutaneous sensor or the like themselves. For

some persons it is a troublesome process to perform the skin penetration themselves, they therefore need a device which assists them in this process and thereby making the process less problematic.

The document US 2003/0225373 discloses an insertion device for inserting an infusion part or a sensor into a patient. The device comprises a housing, a coil spring, a safety device and part for angling the insertion into the patient. However the apparatus is relatively complicated to manufacture industrially and further the device has to be loaded manually by the patient by a rather complicated procedure.

WO 03/026728 A1 discloses an injector device comprising a housing, a spring, a slidable bar, a locking mechanism and a needle.

It is an object of the invention to provide an improved insertion device which is easy to manufacture and which is suitable for being delivered in a loaded form or at least being easier to load. Especially elderly people, who can have some motor problems, need an insertion device which exists in a pre-loaded form.

According to the invention an injector device is provided for the subcutaneous introduction of a cannula of an infusion part into the skin of a patient. The injector device comprises a housing, a back and longitudinally extending guiding means, a member which is longitudinally slidable within the housing, an insertion needle for insertion in the cavity of said cannula, a spring located between the back of the housing and the longitudinally slidable member, locking means for maintaining the spring in a compressed state and release means for disengaging the locking means characterized in that the device further comprises a pivoting member which can be swung from a position in which the pivoting member allows for insertion of the needle into a position in which the pivoting member embraces the needle.

The insertion device according to this invention is easy to handle in a safe way before, during and after use, even if the user has reduced dexterity in the hands. Also the user can choose an essentially vertical insertion which makes it easier to control the dept of the needle penetration and thereby the insertion dept of the cannula. This is important in self-insertion of the infusion part. Besides the injector is of a very simple construction which makes it possible to reduce costs of production.

The insertion needle can during insertion be unreleasably attached to the slidable member, unreleasably attached to the infusion part thereby being the cannula or the insertion needle can be a separate unit which the user removes after insertion.

In a preferred embodiment the pivoting member is fastened to the slidable member. This makes production of the unit simpler, and also the pivoting member will need to be shorter than if the pivoting member was fastened to the housing. If the pivoting member is fastened to the slidable member, the position where the pivoting member allows for insertion of the needle is preferably in an angle v where $v \approx 45°$ or larger in order for the pivoting member to be bend backwards when touching the user, preferably $v \approx 90°$ or larger in order for the pivoting member not to hit the user during insertion. The angle v is the angle between the central axis of the injection device which is parallel to the insertion needle, and the pivoting member.

In a preferred embodiment the insertion device has means for temporarily fixing the pivoting member in an essentially right angle relative to the housing thus stabilizing the insertion device in an essentially vertical position relative to the skin to be penetrated prior to penetration. This is particularly relevant for patients with motor problems since they can have problems to control the insertion angle.

Preferably the housing has means for getting a better grip of the injector device. Examples of such means could be but are not limited to rims, grooves, recesses, a roughened surface optionally of another material than the housing itself, preferably recesses are used

There will be different possibilities for placing the pivoting member in the position where it embraces the needle but in a preferred embodiment the pivoting member embraces the needle when the slidable member is in a forward position and the spring is in a released state. Often when using injection devices in connection with insertion of infusion sets the user is supposed to bring the insertion needle back into the housing in order to protect the surroundings from the used insertion needle. This means the users has to work against the spring force, which was pushing the needle forward during insertion, and at the same time the user has to avoid the used needle, when bringing it back into the housing. This can be quite difficult for a user which might have reduced dexterity of the hands and fingers. According to the present invention it will be quite easy for the user to secure the insertion needle as turning the relatively large pivoting member does not call for the use of strength.

In one embodiment the insertion needle is destroyed and secured as the pivoting member is placed in a final position embracing the needle. This will make it safe to dispose of the used insertion device with ordinary garbage.

In one embodiment the pivoting arms are also the locking means and it has a tab functioning as disengaging means.

In another embodiment there is separate locking means and disengaging means. Preferably the pivoting member then still have a tab for securing the

arm in a position parallel to the axis of the housing until it is desired to swing the pivoting member to the position in which it embraces the needle.

Preferably the pivoting member embraces the needle in a first position being parallel to the main axis of the injector device then it is swung into a second position being essentially orthogonal to said main axis and then finally swung into a position in which it embraces the needle.

In a preferred embodiment the pivoting member is swung from the position essentially orthogonal to said main axis, 180 degrees to another position embracing the needle and being secured in this position said position also being essentially orthogonal to the main axis. Optionally the needle is destroyed in the process and secured in the pivoting member.

In another preferred embodiment the infusion part to be inserted is provided with an adhesive support unreleasably fastened to the infusion part and having an adhesive surface, which adhesive surface is provided with a release liner.

In this embodiment the pivoting member can have fixing means for releasably fastening a part of the adhesive support to the pivoting member. This construction assures that the adhesive support is folded in an appropriate way during insertion, which results in that the adhesive support will turn a part of the adhesive surface towards the user's skin, when the infusion part is inserted.

In another preferred embodiment the release liner of the adhesive support can also have one or more projecting parts. Describing parts as projecting from the release liner means that the parts are not necessarily in contact with the adhesive surface of the adhesive support, the projecting part or parts extend beyond the part of the release liner being in protecting contact with

the adhesive surface. One of the projecting parts can be fastened unreleasably to the housing in order to at least partly have the release liner removed from the adhesive support during insertion of the needle. The total removal of the release liner will take place after insertion of the needle when the injector device is taken away for disposal and the release liner will – as it is still attached to the injection device – be removed and disposed off together with the used injector device.

In a more preferred embodiment the release liner comprises at least two separate pieces, and each piece has at least one projecting part. This makes it possible to remove the release liner automatically during insertion without the release liner coming into conflict with the insertion needle.

Preferably the projecting part of the first piece of release liner is attached to the pivoting member during insertion and the projecting part of the second piece of release liner is attached to the housing during insertion. This embodiment makes it easier for the user to remove the release liner during/after insertion and at the same time the adhesive surface of the adhesive support is completely protected before insertion.

In a preferred embodiment of the invention the pivoting member of the injector device further has means for temporarily fixing the adhesive support of the infusion part. Hereby it is achieved that the adhesive support does not fold in an unsuitable manner during insertion of the infusion part.

Preferably the injector device comprises means for stopping the slidable member in its most forward position preferably in form of a stopping tab.

In a preferred embodiment the injector device has a locking tab for fixing the pivoting member in a position embracing the needle.

In the following the invention will be described in further details with reference to the figures.

Figure 1 shows one embodiment of an infusion set where the infusion part and the connector are unified.

Figure 2 shows one embodiment of the infusion set where the infusion part and the connector are separated.

Figure 3 shows the same embodiment of the separated infusion set as in figure 2 from a different angle.

Figure 4 shows a second embodiment of a separated infusion set from a first angle.

Figure 5 shows the second embodiment of the infusion set from a different angle.

Figure 6 shows a first embodiment of an injector device separated from the infusion part.

Figure 7 shows the first embodiment of the injector device joined with the infusion part.

Figure 8 shows the first embodiment of the injector device joined with the infusion part.

Figure 9 shows the first embodiment of the injector device where the pivoting member is embracing the needle after insertion.

Figure 10 shows the first embodiment of the injector device in the loaded and secured position before insertion.

Figure 11 shows the first embodiment of the injector device in the loaded and secured position before insertion from a second angle.

Figure 12 shows a second embodiment of the injector device in a loaded and secured state before insertion.

Figure 13 shows the second embodiment of the injector device in a ready to use state.

Figure 14 shows the second embodiment of the injector device after insertion of the needle and before removing the injector from the infusion part.

Figure 15 shows the second embodiment of the injector device after separating the injector from the infusion part.

Figure 16 shows the second embodiment of the injector device after the pivoting arm has been positioned to embrace the used needle.

Figure 17 shows the second embodiment of the injector device after the pivoting arm has been positioned to embrace the needle seen from another angle.

Figure 18 shows an infusion set placed on the skin.

Figure 19 shows the second embodiment of the injector device together with a credit card.

Figure 20 shows a third embodiment of the injector device.

Figure 21 A-D shows assembling of the infusion part and injector device according to the third embodiment.

Figure 22 A-B shows the third embodiment of the injector device prepared for insertion.

Figure 23 A-B shows the adhesive support of the infusion part hooked to the slidable member.

Figure 24 A shows the injector device after insertion with an infusion part and figure 24 B shows the injector device after insertion without the infusion part.

Figure 25 shows the third embodiment of the injector device after insertion and embracing the needle.

Figure 26 A-D shows the different steps when injecting the infusion part.

Figure 35 and 36 A-D shows the different steps when using a fifth embodiment of the injector device for injecting the infusion part.

Fig. 1-3 illustrates an embodiment of an infusion set. The infusion set comprises an infusion part (0B) and a connector (0A). The infusion part (0B) comprises a base part (2) having a main plane which, when the infusion set is attached to a patient, is essentially parallel with the skin of the patient. Said base part (2) comprises a first set of guiding means (13) which in this case has the form of two stabilizing fins. The base part further comprises two retention devices (4) extending from the upper surface of the base part in this case in form of two steps. Mounted on the inner surface of the infusion part is an adhesive support (1) which in this case is a plaster. A cannula (5) is extending from the base part (2) and is penetrating the adhesive support (1)

being in fluid communication with a central cavity (3). The cannula (5) is preferably a soft cannula but could also be made of metal. The cavity (3) optionally being covered by a membrane is adapted to receive a cannula (6) extending from the connector. In the embodiment shown in fig. 2-5 the cannula (6) is extending from the central part of the connector and is placed in a retracted position relative to the front of the central part. In this embodiment the base part (2) has two cuttings (12) creating two flaps on which the retention devices (4) are mounted. The connector (0A) comprises two arms (9) having four carvings (10) adapted to fit with the retention devices (4). The connector (0A) is symmetrical around the main plane and around the plane perpendicular to the main plane and parallel to the main axis thus allowing the connector to match with the base part in two ways. The cannula (6) is in fluid communication with the tube (7) which provides the connection to a medical device such as an insulin pump. In this embodiment the central part of the connector has a second set of guiding means (8) in form of two grooves placed symmetrically around the main plane of the connector. In this embodiment the connector further has gripping means (11) in form of recesses. The gripping means 11 are optional and can be selected from the group consisting of rims, grooves, recesses or a roughened surface optionally of another material than the connector itself

Fig. 4 and 5 show another embodiment of the invention where the connector has two grooves (14) which in this case are placed symmetrically around the main plane of the connector. However it is not necessary for the grooves to be places symmetrically around the main plane since they are not coupling with the infusion part.

Whether the infusion set is intended to be inserted manually or by an injector the infusion part (0B) and the connector (0A) are delivered to the user as two separate units in sterile packages. If inserted manually the infusion part (0B) will at delivery be combined with a needle unit with the same locking and

guiding means (8) as the connector. The needle unit is provided with an insertion needle extending from the central front which insertion needle at delivery extends through and beyond the end of the cannula (5). The needle unit's only function will be to penetrate the user's skin where after the needle unit is removed and replaced with the connector (0A) leaving the cannula (5) subcutaneous.

The connector (0A) can be connected to a luer coupling member through the tube (7). Through the luer coupling it is possible to administer a suitable therapeutical substance, such as insulin from a pump. The connector can also be a sort of closing part with a suitable entrance for the inserting needle of a syringe. Such a closing part can stay in position for up till three days while the user can have medication, e.g. insulin injected through the entrance in order to reduce trauma to the skin.

It is important for the user that it is easy to change i.e. to engage and to disengage the infusion part (0B) and the connector (0A) even when the user has reduced dexterity of hands and fingers. The present infusion set complies with this purpose as the movement used to unlock the infusion part (0B) from the connector (0A) is pressing the connector between the first finger and the thumb which is a simple and easily performed movement. Also the oppositely directed forces from respectively the first finger and the thumb pushing toward each other, are not only used to unlock the device but is also used when pulling the connector away from the infusion part (0B). In order to make it easier to disengage the connector (0A) the arms (9) can be made very flexible, either by choosing a soft and flexible material or by making the fastening of the arms (9) to the central part more or less rigid e.g. by varying the size of the grooves (14) on the shoulder of the connector (0A).

Although the arms (9) are very flexible the danger of accidently releasing and pulling the connector away from the infusion part, when positioned on the

skin of the user, is quite small as the device has to be exposed to a simultaneous pressure from both sides.

Fig. 6 -11 shows a first embodiment of an injector device (29) which can be used for injection of the infusion part (0B) of the infusion set. In fig. 6 the injector device is separated from the infusion part (0B) and fig. 7 and 8 show the same injector device (29) joined with an infusion part (0B). The injector device comprises a housing (30) with two longitudinally extending guiding means (31) formed as grooves in this embodiment and a longitudinally slidable member (32) having guiding means (31a), in this embodiment a rim, corresponding to the guiding means (31). A penetrating needle (35) is extending from the front part of the slidable member (32), and the needle (35) is at the end where it is fastened to the slidable member (32) surrounded by guiding means corresponding to the guiding means (13) on the infusion part (0B). The slidable member (32) is capable of moving from a retracted position to a forward position, and is driven from the retracted position to the forward position by a spring (34). The spring is located between the slidable member (32) and the back (33) of the housing. Optionally there is a spring support (37) (fig. 8) which fits with the back of the housing thereby minimizing the risk of a malfunctioning spring. The injector device further comprises locking means (38) for maintaining the spring in a compressed state and release means (39) for disengaging the locking means. When the locking means (38) are disengaged, the spring (34) drives the slidable member (32) to its forward position, thus introducing the cannula positioned at the front end of the infusion part (0B) into the patient by means of the needle (35). After the introduction of the cannula, the injector device including the insertion needle (35) is withdrawn from the infusion part (0B) leaving the insertion needle in an exposed position. The pivoting member (36) can then be swung into a position where it embraces the needle (35) as shown in fig. 9.

Fig. 10 and fig. 11 show the same embodiment of the injector device in a loaded and secured position. Part of the pivoting member (36) acts as locking means (38). In Figure 10 it can be seen how the needle (35) fits into the cannula (5) of the infusion part. The needle (35) will bring the cannula (5) with it during the skin penetration. After penetrating the skin the needle (35) secured to the injector will be withdrawn leaving the cannula inserted in the patient. In fig. 11 the locking means are shown said locking means are disengaged when the tab (38) is pushed over the edge of the outer side of the back (33) of the housing.

Figures 12 to 17 show a second embodiment of the injector device according to the invention where the pivoting member (36) is fastened centrally in relation to the slidable member (32). Figure 12 shows the injector device in a state where the pivoting member (36) protects the needle prior to injection of the cannula (5) of the infusion part (0B). The figure shows the housing (30) with another type of longitudinally extending guiding means (31), in this case a bar. The housing further has gripping means (40), preferably in the form of recesses, as means for getting a better grip of the injector device.

Centrally positioned release means (39) is shown on one of the main faces of the injector device. The advantage of a one button release mechanism is that the risk of a slanting injection reduced.

In fig. 13 is shown an injector device prepared for insertion of the needle. The pivoting member is positioned away from the embracing position in an angle $v \approx 90°$ in relation to the main axis of the injector device where the main axis is coincident with the insertion needle. The adhesive support (1) is positioned in such manner that the cannula (5) of the infusion part (0B) and the therein positioned needle (35) penetrates the adhesive support through an opening in the release liner. When the pivoting member is positioned essentially perpendicular to the main plane of the injector device it can provide a helping

mean for achieving essentially vertical injection of the needle. Further fig. 13 shows the needle (35) of the injector device inside the cannula (5). In fig. 14 the injector device is in a released state where the needle (35) would have penetrated the skin. The housing in the embodiment of fig. 14 has a stopping tab (43) corresponding to a protrusion on the slidable member that keeps the slidable member (32) within the housing (30) thereby making it easier to withdraw the needle since there is no risk that the slidable member slides out of the housing. In fig. 15 the injector device has been withdrawn, leaving the cannula (5) of the infusion part (0B) inserted in the patient. In fig. 16 and 17 the pivoting member (36) is in a position where it embraces the needle (35) thereby protecting the surroundings from coming into contact with the used needle (35). In fig. 18 the infusion part (0B) has been brought from the essentially vertical insertion position to a position essentially parallel to the skin.

Fig. 19 shows the injector device together with a credit card to illustrate the size of the injector device.

In fig. 20 is shown a third embodiment of the injector device together with an infusion part (0B). This embodiment also has a housing (30) with longitudinally extending guiding means (31) and a longitudinally slidable member (32) of a different construction compared to the two first embodiments. Also the pivoting arm (36) and the spring (34) can be seen in this figure. In this embodiment the stopping tab (43) is placed centrally and has the form of a protrusion raising form the lower side of the housing (30). The release means (39) comprises two buttons placed on each side of the housing (30).

In fig. 21 A-D it is shown how the infusion part (0B) along with the slidable member (32) and the spring (34) of the third embodiment fit into the housing (30). The unit (?) shown between the pivoting arm (36) and the insertion part

(0B) is an adapter which makes it possible to use a standard injector for different guiding means (13) on the infusion part (0B).

In fig. 22 A-B is shown fixing means (44) placed on the pivoting member (36). It is possible to temporarily attach a part of the adhesive support (1) to the fixing means in order to secure the position of the adhesive support in such a way that the adhesive surface of the support (1) will be turned towards the skin of the patient. Further release means (39) in the form of two buttons, one on each side of the housing (30), can be seen as well as the protruding stopping tab (43).

Fig. 23 A-B shows in further details and without the housing how the adhesive support (1) is hooked to the fixing means (44) due to at least one cutting (46) in the adhesive support (1).

Fig. 24 A shows the third embodiment of the injector device with an infusion part after insertion and 24 B shows the injector device after insertion and after the injector device has been removed from the insertion part (0B).

In fig. 25 the pivoting member (36) of the injector device is in a position embracing the needle. A locking tab (45) fixes the pivoting arm in this position. This makes certain that the needle stays embraced by the pivoting arm and thereby minimizes the risk of somebody getting hurt by the needle.

In fig. 26 A-D the cycle of use for the injector device is illustrated:
When the infusion set is delivered to the patient together with the injector device, the infusion part (0B) and the connector (0A) are packed separately and under sterile conditions, and the infusion part (0B) is placed in the injector device (fig. 26 A). When the user wants to insert the infusion part (0B), the user pulls the pivoting arm and turns the arm perpendicularly to the housing (30) (fig. 26 B). In this position the needle (35) placed on the slidable

member (32) is exposed and the adhesive support is bend backwards with the adhesive surface turned towards the users skin. The user then pushes the buttons (39) on each side of the housing which releases the spring and pushes the slidable member (32) towards the user's skin (fig. 26 C). The needle (35) will in this position penetrate the skin and place the cannula of the infusion part (0B) subcutaneous. After placing the infusion part (0B) the injector device is removed, and in order to protect the surroundings from the used needle (35) the pivoting arm (36) is turned approximately 180° to an angle w ≈ 90° perpendicular to the main axis of the injector device, where it embraces the needle and make it safer to dispose of the device.

Fig. 35A-E and 36A-E illustrates the cycle of use of the injector device seen respectively from the upper (fig. 35) and the lower (fig. 36) side of the injector device.

In fig. 35A and 36A the device is in a first state, which is the state the device would normally be delivered to the patient in, under sterile conditions. In this state the pivoting arm (36) is in a position where it embraces the needle (35) and the angle v between the main plane of the injector device and the pivoting arm is approximately 0°, if the release means (39) should unintentionally be pressed in this situation two protruding tabs (48) will prevent the slidable member (32) from being pushed forward.

In fig. 35B and 36B the device is prepared for use by lifting the pivoting arm (36) backwards thereby exposing the insertion needle (35) and also in this embodiment lifting the part of the release liner (41) which is attached to the pivoting arm (36), exposing the underlying adhesive support (1). In this position the pivoting arm (36) allows for insertion of the needle and is in an angle v to main plane of the injector device where 90°≤ v ≤180°, and in this position the injector device would be placed against the patient's skin.

In fig. 35C and 36C the release means (39) has been pressed and has released the spring (34). The spring has pushed the slidable member (32) forward until the slidable member was stopped by two stopping tabs (43). In this position the insertion needle (35) has penetrated the patient's skin and a part (this part covers an area around the needle in the full breadth of the adhesive support) of the adhesive surface of the adhesive support (1) is in contact with the patient's skin. In fig. 36C it is shown how the second part (42) of the release liner is attached to the housing (30) and still covers the adhesive surface when the slidable member (32) is pushed forward.

In fig. 35D and 36D it is shown what happens when the injector device is removed from the patient, leaving the infusion part (0B) inserted subcutaneously. The user frees the first part (41) of the release liner from the pivoting arm (36) and then when pulling the injector device away the second part (42) of the release liner is also pulled away, exposing the adhesive surface of the adhesive support (1) and making it possible for the user to press the adhesive support towards the skin and thereby securing the infusion part (0B).

Finally after withdrawal of the insertion needle which in this embodiment is attached to the slidable member (32) in the injector device, it is shown in fig. 35E and 36E how the pivoting member (36) is placed in a position where it is embracing the needle thereby protecting the surroundings from getting stung. In order to get into this position the pivoting arm (36) is turned approximately 180° from the position in fig. 35D and 36D, and the angle w between the main plane of the injector device and the pivoting arm (36) is approximately 90°.